

INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP2004/014475

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 5, 8

because they relate to subject matter not required to be searched by this Authority, namely:

The inventions as set forth in claims 5 and 8 pertain to methods for treatment of the human body by therapy. (Article 17(2) (a) (i) of the PCT, Rule 39.1(iv) of the Regulations under the PCT)

2. Claims Nos.:

because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.:

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

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Claims 1 to 4, 6 and 7

In the inventions according to these claims, a dipeptidyl-peptidase IV inhibitor is employed as the active ingredient. Although it can be judged, based on these statements, whether or not individual compounds are dipeptidyl-peptidase IV inhibitors, no clear definition is made in the description on the specific chemical structure of the dipeptidyl-peptidase IV inhibitor. Moreover, such a structure is not self-evident for a person skilled in the art. Thus, the statements fail to make the structure clear.

In the case of specifying the active ingredient depending on its function and thus involving compounds of various chemical structures in the scope thereof as in the present application, it was a common technical knowledge at the point of the application that any compound having such a function could not be considered as having a specific pharmacological effect. Therefore, it is needed to present pharmacological data obtained by a specific pharmacological test or theoretical discussion in the description at such a level as allowing general recognition that the compounds having the above function have the specific pharmacological effect. In the description of the present case, however, a test was performed merely on one compound and it was not confirmed that the same effect could be achieved generally by the compounds having the same function.

Thus, it cannot be considered that the description discloses the inventions in a manner sufficiently clear and complete for the inventions to be carried out by a person skilled in the art, and the inventions are not sufficiently supported thereby (PCT Articles 5 and 6).

Such being the case, prior art documents were examined in preparing this international search report exclusively in a rational range based on the statements in EXAMPLES.

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A. CLASSIFICATION OF SUBJECT MATTER
Int.Cl⁷ A61K45/00, 31/472, A61P3/10, 5/50//C07D217/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Int.Cl⁷ A61K45/00-45/08, 31/00-31/80, A61P1/00-43/00, C07D217/00-217/24

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
JSTPLUS (JOIS), JMEDPLUS (JOIS), MEDLINE (STN), EMBASE (STN), BIOSIS (STN), BIOTECHABS (STN), CAPLUS (STN)**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	Hiroshi KIYONO et al., "Sui β Saibo ATP Kanjusei K ⁺ Channel to Sulfonylure Receptor no Kino Kyokan no Kaiseki, Oyobi Atarashii Sayo Kijo ni yoru Keiko Tonyoboyoyaku no Kaihatsu", Research papers of the Suzuken Memorial Foundation 1999, Suzuken Memorial Foundation, 2001, pages 147 to 149	1-4, 6, 7
Y	FABGHANEL, G. et al., Metformin's Effects on Glucose and Lipid Metabolism in Patients with Secondary Failure to Sulfonylureas. Diabetes Care, 1996, 19(11), pages 1185 to 1189	1-4, 6, 7

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
14 December, 2004 (14.12.04)Date of mailing of the international search report
28 December, 2004 (28.12.04)Name and mailing address of the ISA/
Japanese Patent Office

Authorized officer

Facsimile No.

Telephone No.

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
Y	Kentaro YAMADA, "Keiko Yakubutsu Ryoho no Shinsenryaku 2. Keiko Ketto Tokayaku no Tsukaiwake to Heiyo", Tonyobyogaku no Shinpo, 2002, 36, pages 292 to 296	1-4, 6, 7
Y	TRISCHITTA, V. et al., Comparison of Combined Therapies in Treatment of Secondary Failure to Glyburide. Diabetes Care, 1992, 15(4), pages 539 to 542	1-4, 6, 7
Y	JP 2003-238566 A (Takeda Chemical Industries, Ltd.), 27 August, 2003 (27.08.03), Claims; examples; Par Nos. [0002], [0046] to [0057] & WO 02/62764 A1 & NO 200303385 A & EP 1355886 A1 & KR 2003074774 A & AU 2002230126 A1 & US 2004/082607 A1 & CZ 200302321 A3 & SK 200301080 A3 & HU 200400058 A2 & BR 200206831 A & CN 1500080 A	1-4, 6, 7
Y	Yoshiro KITAHARA et al., "Tonyobyo Ippan ni Kansuru Chiryoyaku- Sokkogata Insulin Bunpitsu Sokushinzai ni yoru Seiritekina 'To no Nagare' no Jitsugen-", Saibo, 2000, 32(12), pages 480 to 483	3
L	"SU-zai ni 2ji Muko to Kangaerareru 2gata Tonyobyo Kanja ni okeru Chosokkogata Insulin Bunpitsu Sokushinzai nateglinide(Na) no Koka", The journal of the Japan Diabetic Society, 2000, 43(suppl.1), p.S-120 (Sulfonylurea 2ji Muko o Hikiokosu Seibun to Sareru Nateglinide ni yori, Sulfonylurea 2ji Muko Tonyobyo ga Chiryo Sarerukotoga Kisai Sareteiru.)	3
L	"2gata Tonyobyo Kanja no Sulfonylurea-zai 2ji Mukorei ni Taisuru Sokkogata Shokugo Ketto Tokazai (Nateglinide) no Shiyo Keiken", Nippon Taishitsugaku Zasshi, 2001, 63(1-2), page 52 (Sulfonylurea 2ji Muko o Hikiokosu Seibun to Sareru Nateglinide ni yori, Sulfonylurea 2ji Muko Tonyobyo ga Chiryo Sarerukotoga Kisai Sareteiru.)	3